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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,576	08/09/2001	Carsten Andersen	10004.204-US	2881

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EXAMINER	
RAO, MANJUNATH N	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,576	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-30,50 and 57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-30,50 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence alignments(11 p)*.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER APPEAL BUT BEFORE A BOARD DECISION

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2-9-06 has been entered.

Claims 25-30, 50, 57 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 1-17-06 and 2-9-06, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Specifically, Examiner has withdrawn the rejection under 35 U.S.C. 112, 2nd paragraph and the rejection under 35 U.S.C. 102(b) in view of claim amendments and claim cancellations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 and claims 26-30, 50, 57 which depend from claim 25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 25 is now drawn to " non-naturally occurring variant of a parent α-amylase.." comprising specific amino acid changes wherein said variant has amylase activity and wherein said variants has an amino acid sequence homology of at least 90% to SEQ D NO:12. However, a perusal of the specification indicates that applicants have no support for the phrase "non-naturally occurring" which now constitutes a "new matter". Therefore claim 25 and claims 26-30, 50, 57 which depend from claim 25 are rejected for introducing "new matter" into the claims. Applicants have failed to provide or point out the support in the specification for the above phrase and a perusal of the specification by the Examiner also did not provide any support for the above mentioned amendment.

Claims 25-30, 50, 57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a variant amylase enzyme of SEQ ID NO:12 wherein the variant comprises an alteration selected from the group of alterations to amino acid at positions 118, 320 or 458 and wherein the alteration specifically comprises replacing the amino acid at said positions with lysine (K), does not reasonably provide enablement for variant amylase enzyme wherein the variant comprises a polypeptide having at least 90%, 95% or 97% homology with SEQ ID NO: 12, as well as an alteration selected from the group of alterations corresponding to amino acid at position 118, 320 or 458 and wherein the alteration specifically

comprises replacing the amino acid at said positions with lysine (K). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 25-30, 50, 57 are so broad as to encompass any amylase comprising the modifications at the above mentioned three positions and having 90% through 97% identity to SEQ ID NO: 12. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of amylases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the variant amino acid sequence of only SEQ ID NO:12 selected from the group of alterations to amino acid at positions 118, 320 or 458 and wherein the alteration specifically comprises replacing the amino acid at said positions with lysine (K). It would require undue experimentation of the

skilled artisan to make and use the claimed polypeptides. The specification is limited to teaching the use of SEQ ID NO: 12 with the any one of the above three amino acid modifications as a amylase but provides no guidance with regard to the making of variants and mutants that are 90% to 97% identical to SEQ ID NO 12 or with regard to other uses. In view of the great breadth of the claim, amount of experimentation required to make the claimed polypeptides, the lack of guidance, working examples, and unpredictability of the art in predicting function from a polypeptide primary structure (e.g., see Ngo et al. in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495), the claimed invention would require undue experimentation. As such, the specification fails to teach one of ordinary skill how to use the full scope of the polypeptides encompassed by this claim.

While enzyme isolation techniques, recombinant and mutagenesis techniques are known, and it is routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the instant claims, the specific amino acid positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any amylase with 90% through 97% identity to SEQ ID NO: 12, because the specification does not establish: (A) regions of the protein structure which may be modified without affecting amylase activity; (B) the general tolerance of amylases to

modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including amylases with an enormous number of amino acid modifications to SEQ ID NOS: 12. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

In response to the previous Office action, applicant has traversed the above rejection arguing that the amended claims are directed to variants having a high degree of homology to SEQ ID NO:12 and that the specification describes many α amylases falling within the claimed invention . Applicant provides few examples of such variants. Applicant also argues that the specification provides working examples of α amylases homologous to SEQ ID NO:12 and provides table suggesting specific amino acid changes. Applicant also argues that the specification describes methods which are well known in the art for practicing the invention and three dimensional structures and crystal structure of Termamyl-like α amylases and methods to determine the conserved sequences. Examiner respectfully disagrees with such an argument as being persuasive to overcome the above rejection. First of all it must be recognized that

applicant does not disclose or describe all those sequences that are 90% homologous to SEQ ID NO:12, even though the specification does indicate few specific variants. Furthermore, while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Instant claims sequences that are 90% through 97% identical to SEQ ID NO:12. Thus, in order to make the full scope of recited polypeptides, one skilled in the art has to modify up to approximately 10% of the nucleotides of the sequence of SEQ ID NO:12, comprising 485 amino acids. As noted in the Office action, the polypeptide variants encompass those having a single amino acid substitution, addition, deletion, or insertion and any combination of amino acid substitutions, additions, deletions, and/or insertions. Although the claims are not limited to variants having only a single amino acid substitution, in order to generate for example, only single amino acid variants of each amino acid of SEQ ID NO:12, one must make 19^{485} variants – just for *single amino acid variants*. Thus, at a minimum, the number of variants is 19^{485} and the number becomes seemingly infinite when one considers that the claims broadly encompass simultaneous other alterations by substitution, addition, deletion, and/or insertion. Therefore, while methods to produce variants of a known sequence, e.g., site-specific mutagenesis and random mutagenesis, are well-known to the skilled artisan, producing the claimed variants requires that one of skill in the art know or be provided with guidance for the selection of which of the at least 19^{485} variants has the desired activity. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the at least 19^{485} possible variants. The art clearly *does*

not typically engage in the screening of 19^{485} single amino acid variants and it follows that the art does not typically engage in the screening of $>19^{485}$ variants to isolate those relatively few variants that would have the desired activity. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As such, based on a determination by weighing all of the factual considerations of In re Wands, the examiner has made a determination that the specification does not enable the claimed invention without undue experimentation. Hence the above rejection is maintained.

Claims 25-30, 50, 57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 25-30, 50, 57 are directed to " non-naturally occurring variant of a parent α-amylase.." wherein said variants have amylase activity, specific amino acid position changes and an amino acid sequence homology between 90% and 97% to SEQ ID NO:12. Claims 25-30, 50, 57 are rejected under this section of 35 USC 112 because the claims are directed to a genus of non-naturally occurring variants. This rejection has been made because the Examiner maintains the position that the single representative disclosed species, i.e., SEQ ID NO:12, comprising

changes at positions 118, 320 and 458 fails to represent the entire genus of claimed non-naturally occurring variants (underline added for emphasis).

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. In the instant specification, a single non-naturally occurring variant polypeptide is described as SEQ ID NO:12 having said changes and activity. This description also adequately describes a genus, within the sequence identity limitation of the instant claims, of polypeptides having this particular structure and function. Those sequences that are " non-naturally occurring variants " are a subset of this genus of polypeptides having amino acid sequence identity to SEQ ID NO:12 and having amylase activity. The specification fails to define those structural features of SEQ ID NO:12 that are commonly possessed by members of the genus that distinguish them from other "naturally occurring variant" polypeptides. Thus, one skilled in the art cannot visualize or recognize the

identity of the members of the genus. As such, this single representative species does not adequately describe this subset according to its structure so that one of skill in the art can visualize and distinguish those amino acid sequences that are natural variants and non-naturally occurring variants, particularly in view of the larger genus that includes both natural and non-natural sequences. Therefore, the instant claims are not adequately described.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 25, 27-28, 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Outtrup et al. (US 5,824,531, Issued 10-20-1998, and US 5856164, issued Jan 1999). This rejection is based upon the public availability of patents. Claims 25, 27-28, 30 of the instant application are drawn to a variant of a parent α-amylase, wherein said variant comprises a substitution of a K at an amino acid position selected from the group consisting of 118, 320 and 458 wherein said variant has α amylase activity and an amino acid sequence of at least 90% homology to SEQ ID NO:12. Outtrup et al. disclose such a variant wherein said variant comprises a substitution of a K at amino acid positions 320 and 458 wherein said variant has α amylase activity and an amino acid sequence that is 90% identical to SEQ ID NO:12. The reference does not make it clear whether said parent of the variant is *Bacillus sp.* DSMZ no. 12649 α amylase. However, Examiner takes the position that because the variant satisfies all the claim requirements, the parent of said variant is inherently a *Bacillus sp.* DSMZ no. 12649 α amylase. Therefore, Outtrup et al. anticipate claims 25, 27-28 and 30 as written.

Since the Office does not have the facilities for examining and comparing applicants' parent protein with the parent protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the parent of the claimed product and the parent enzyme of the product of the prior art (i.e., that the parent protein of the prior art does not possess the same material structural and functional characteristics of the parent of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

Claims 25, 27-28, 30 are rejected under 35 U.S.C. 102(e) as being anticipated by the following twelve US Patents 6093562, 6187576, 6197565, 6204232, 6287826, 6297038, 6361989, 6486113, 6528298, 6673589, 6867031, 6887986. This rejection is based upon patents issued to other inventive entities. Claims 25, 27-28, 30 of the instant application are drawn to a variant of a parent α-amylase, wherein said variant comprises a substitution of a K at an amino acid position selected from the group consisting of 118, 320 and 458 wherein said variant has α amylase activity and an amino acid sequence of at least 90% homology to SEQ ID NO:12. The above references disclose such a variant wherein said variant comprises a substitution of a K at amino acid positions 320 and 458 wherein said variant has α amylase activity and an amino acid sequence that is 90% identical to SEQ ID NO:12. The reference does not make it clear whether said parent of the variant is *Bacillus sp.* DSMZ no. 12649 α amylase. However, Examiner takes the position that because the variant satisfies all the claim requirements, the parent of said variant is inherently a *Bacillus sp.* DSMZ no. 12649 α amylase. Therefore, Outtrup et al. anticipate claims 25, 27-28 and 30 as written.

Since the Office does not have the facilities for examining and comparing applicants' parent protein with the parent protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the parent of the claimed product and the parent enzyme of the product of the prior art (i.e., that the parent protein of the prior art does not possess the same material structural and functional characteristics of the parent of the claimed protein). See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 27-28, 30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patents 6093562, 6187576, 6197565, 6204232, 6297038, 6673589. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 25, 27-28, 30 of the instant application and claims in the reference patents are both directed to variants of amylase having an amino acid sequence that is at least 90% identical to SEQ ID NO:12 and comprising an alteration at an amino acid corresponding to positions 320 and 458 (R to K). Among the different positions claimed in the instant application and in the reference patents the above positions are identical to the positions recited/claimed in all the reference patents. The portion

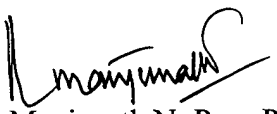
of the specification (and the claims) in the reference patents that supports the recited amino acid positions on SEQ ID NO:12 herein includes the embodiments (amino acid positions and amino acid percent identity) that would anticipate the positions claimed in claims 25, 27-28, 30 herein. Claims of the instant application listed above cannot be considered patentably distinct over claims of the reference patents when there is specifically recited embodiment that would anticipate mainly claims 25, 27-28, 30 of the instant application. Alternatively, claims 25, 27-28, 30 cannot be considered patentably distinct over claims of the reference patents when there is specifically disclosed embodiment in the reference patents that supports claims of that patent and falls within the scope of claims 25, 27-28, 30 herein because it would have been obvious to one having ordinary skill in the art to modify claims of the reference by selecting a specifically disclosed embodiment that supports those claims i.e., a variant of a parent glucoamylase with SEQ ID NO:12 comprising changes at positions 320 and 458 and an amino acid sequence that is at least 90% identical to SEQ ID NO:12. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within claims of the reference patent.

Conclusion

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura

Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306/9307 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

May 23, 2006